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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,691	06/03/2002	Stephen Gill	PA-9947	3741
22840	7590	05/28/2004	EXAMINER	
AMERSHAM BIOSCIENCES PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855			HARTLEY, MICHAEL G	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/069,691	<b>Applicant(s)</b> GILL ET AL.	
	<b>Examiner</b> Michael G. Hartley	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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***Response to Amendment***

The preliminary amendment filed 21 Feb 2002 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by JP 11099192.

JP '192 discloses a composition comprising a stabilizer suitable for a metal complex (e.g. chloride) in a container that has a silica coating on the inner surface. Note: the intended use, "for the preparation of a stabilized radiopharmaceutical complex" has not been given patentable weight, as it is merely an intended use recitation. Also, "suitable for" is not a limitation in any patentable sense, but only requires the ability to so perform. Since chlorine can help stabilize a radiometal complex, the chlorine of the thallium chloride is within the scope of a stabilizer, given its broadest reasonable interpretation.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crane (US 5,961,952) in view of any one of JP 11099192 or Schott Glaswerke (DE 29609958) or Walther (US 6,200,658).

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Crane discloses a radiopharmaceutical comprising a solution of a metal complex, i.e., an organic ligand (t-butyl isonitrile) complexed with Tc-99m), see abstract. Crane discloses that the radiopharmaceutical compositions are in kit forms containing various components that may be lyophilized and are contained in vials, see column 6. The compositions contain a bacteriostat, such as, a paraben, see column 7, lines 42-46.

Crane fails to disclose that the vials are silica coated on the inside.

However it is known in the art that vials that are silica coated on the inside are useful for pharmaceuticals, as well as, radiopharmaceuticals, as shown by JP 11099192 or Schott Glaswerke (DE 29609958) and/or Walther (US 6,200,658).

JP '192 discloses that glass containers with a silica coated inner surface provides vials having the advantage of accurate measuring of the radiopharmaceutical, see abstract.

DE '958 discloses glass containers or vials that are coated on the inside with silica provide the advantage of minimizing the amount of ions that are leached out of the glass into the solution and are especially useful for storing pharmaceutical or diagnostic solutions (e.g., by providing a stabilizing effect), see abstract.

Walther teaches that it is known in the art to use glass vials that are coated on the inner surface with silica (e.g., using a PCVD process) for containing pharmaceuticals since such vials avoid the disadvantages of dealkalizing process of glass containers, see column 2.

It would have been obvious to one of ordinary skill in the art to modify the compositions disclosed by Crane (i.e., Tc-99m-ligand complex radiopharmaceutical diagnostic agent) by using vials having a silica coated inside because it is known in the art that such vials provide various advantages for the storage of pharmaceuticals, specifically including diagnostic agents and radiopharmaceuticals, as taught by JP' 192, DE '958 and Wather, as stated above. One of ordinary skill in the art would have been motivated to use such improved silica coated vials for the pharmaceutical compositions disclosed by Crane to take advantage of one or all of the advantages taught in the prior art in using such vials for pharmaceuticals, as stated above. Also, it would have been obvious to one of ordinary skill in the art to use a PCVD process therefore, as this is a well known means of preparing such vials as taught by

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Wather (note, however, that this limitation is a product by process limitation, and the claims have been interpreted as directed to the product itself).

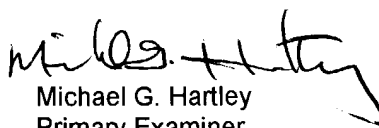
***Conclusion***

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

5/25/2004